Department of Health and Human Services
Food and Drug Administration

Milk Plant, Receiving Station or Transfer Station
HACPP SYSTEM AUDIT REPORT

DATE	TYPE OF AUDIT
	☐ State Regulatory* ☐ State Regulatory Follow-up ☐ State Listing ☐ FDA Audit of Listing

FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.

ADDRESS *(Line 1)*

ADDRESS *(Line 2)*	CITY	STATE	ZIP

IMS LISTED PRODUCT(S) MANUFACTURED & REVIEWED	Prerequisite Program(s) Issue Date(s)

Hazard Analysis ☐ Yes ☐ No Issue Date: _____	HACCP Plan ☐ Yes ☐ No Issue Date: _____

ITEMS MARKED *DID NOT* MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW

Starred ★★ Items are Critical Listing Elements

*__NOTE:__ This regulatory NCIMS System Audit Report of your plant serves as a notification of the intent to suspend your permit if items marked on this audit report are not in compliance at the time of the next regulatory audit or within established timelines. (See PMO Section 5 and Appendix K. for details.)

Section 1 HAZARD ANALYSIS

☐ A. Flow Diagram and Hazard Analysis conducted & written for each kind of group of milk or milk product processed.**

☐ B. Written Hazard analysis identifies all potential food safety hazards & determines those that are reasonably likely to occur (including hazards within & outside the processing plant environment).

☐ C. Written Hazard analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers.

☐ D. Written Hazard analysis signed and dated as required.

Section 2 HACCP PLAN

☐ A. Written HACCP plan prepared for each kind or group of milk or milk product processed.**

☐ B. Written HACCP plan implemented.

☐ C. Written HACCP plan identifies all food safety hazards that are reasonably likely to occur.

☐ D. Written HACCP plan signed and dated as required.

Section 3 HACCP PLAN CRITICAL CONTROL POINTS (CCP)

☐ A. HACCP plan lists CCP(s) for each food safety hazard identified as reasonably likely to occur.

☐ B. CCP(s) identified are adequate control measures for the food safety hazard(s) identified.

☐ C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.

Section 4 HACCP PLAN CRITICAL LIMITS (CL)

☐ A. HACCP plan lists critical limits for each CCP.

☐ B. CL(s) are adequate to control the hazard identified.**

☐ C. CL(s) are achievable with existing monitoring instruments or procedures.

☐ D. CL(s) are met.

Section 5 HACCP PLAN MONITORING

☐ A. HACCP plan defines monitoring procedures for each critical control point. ***(what, how, frequency, whom)***

☐ B. Monitoring procedures as defined in the HACCP plan followed.

☐ C. Monitoring procedures as defined in the HACCP plan adequately measure critical limits at each critical control point.

☐ D. Monitoring record data consistent with the actual value(s) observed during the audit.

Section 6 HACCP PLAN CORRECTIVE ACTION

☐ A. Corrective actions when defined in the HACCP plan were followed when deviations occurred.

☐ B. Predetermined corrective actions defined in the HACCP plan ensure the cause of the deviation is corrected.

☐ C. Corrective action taken for products produced during a deviation from critical limits defined in the HACCP plan.**

☐ D. Affected product produced during the deviation segregated and held, **AND** a review to determine product acceptability performed, **AND** Corrective action taken to ensure that no adulterated and/or product that is injurious to health enters commerce.

☐ E. Cause of deviation was corrected.

☐ F. Reassessment of HACCP Plan performed and modified accordingly.

☐ G. Corrective actions documented.

Section 7 HACCP PLAN VERIFICATION & VALIDATION

☐ A. HACCP plan defines verification procedures, including frequency.

☐ B. Verification activities are conducted & comply with HACCP Plan.

☐ C. Reassessment of HACCP plan conducted annually, **OR**

- ☐ 1. After changes that could affect the hazard analysis, **OR**
- ☐ 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer.

☐ D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP plan.**

☐ E. CCP monitoring records reviewed and document that values are within critical limits as required.

☐ F. Corrective action record reviewed as required.

☐ G. Calibration records and end product or in process testing results defined in HACCP Plan reviewed as required.

☐ H. Records reviewed as required – including date and signature

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ITEMS MARKED *DID NOT* MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW

Starred ★★ Items are Critical Listing Elements

Section 8 HACCP SYSTEM RECORDS

- ☐ A. Required information included in the record - e.g. name/location of processor &/or date/time of activity &/or signature/initials of person performing operation &/or identity of product/product code.
- ☐ B. Processing/other information entered on record at time observed.
- ☐ C. Records retained as required - e.g. one year for refrigerated products/ two years for preserved, shelf-stable or frozen products.
- ☐ D. Records relating to adequacy of equipment or processes retained for 2 years.
- ☐ E. HACCP records correct, complete and available for official review
- ☐ F. Information on HACCP records not falsified.**

Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS

- ☐ A. Required Prerequisite program (PP) written, implemented & in substantial compliance by firm.
  - ☐ 1. Safety of the water that comes into contact with food or food contact surfaces (including steam & ice);
  - ☐ 2. Condition and cleanliness of equipment food contact surface.
  - ☐ 3. Prevention of cross contamination from unsanitary objects & or practices to food products, packaging material & other food contact surfaces, including utensils, gloves, outer garments, etc, & from raw product to processed product;
  - ☐ 4. Maintenance of hand washing, hand sanitizing, & toilet facilities;
  - ☐ 5. Protection of food, food packaging material, & food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate & other chemical, physical & biological contaminants;
  - ☐ 6. Proper labeling, storage, & use of toxic compounds.
  - ☐ 7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, & food contact surfaces; and
  - ☐ 8. Pest exclusion from the food plant.
- ☐ B. Additional PP's required or justified by the hazard analysis are written & implemented by firm.
- ☐ C. PP conditions & practices monitored as required
- ☐ D. PP monitoring performed at a frequency to ensure conformance.
- ☐ E. Corrections performed in a timely manner when PP monitoring records reflect deficiencies or non-conformities.
- ☐ F. PP audited by firm.
- ☐ G. PP monitoring records adequately reflect conditions observed.
- ☐ H. Prerequisite program signed and dated as required.

Section 10 OTHER NCIMS REQUIREMENTS

- ☐ A. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing.**
- ☐ B. Drug residue control program implemented.**
- ☐ C. Drug residue control program records complete.
- ☐ D. Labeling compliance as required.
- ☐ E. Prevention of adulteration of milk products.
- ☐ F. Regulatory samples comply with standards.
- ☐ G. Pasteurization Equipment design and construction.
- ☐ H. Approved Laboratory Utilized - (if not, Rating not conducted)
- ☐ I. Other items as noted.

Section 11 HACCP SYSTEM TRAINING

- ☐ A. Employees trained in monitoring operations.
- ☐ B. HACCP plan reassessment performed by trained individual.
- ☐ C. Records review performed by trained individual.
- ☐ D. Employees trained in prerequisite program operations.

Section 12 HACCP SYSTEM AUDIT FOLLOW-UP ACTION

- ☐ A. Previous audit findings corrected.
- ☐ B. Previous audit findings remain corrected at time of this audit.
- ☐ C. State Milk Plant, Receiving Station or Transfer Station HACCP SYSTEM AUDIT REPORT issued and follow- up conducted as required (HACCP Listing Audits & FDA Audits only).
- ☐ D. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to food safety.**

See attached Audit Discussion sheet(s) for details.

NAME OF AUDITOR(S) *(Please Print)*

SIGNATURE	DATE
SIGNATURE	DATE
SIGNATURE	DATE

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME	DATE OF AUDIT

Provide explanation below of deviation/deficiencies/non-conformities that did not meet the NCIMS HACCP program criteria.

(Use additional sheets as necessary if entry field is non-expandable.)

NOTE: When State Regulatory Audits are conducted, timelines for corrections of all identified deviations, deficiencies and non-conformities must be established.